

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox (US 4695274). Fox discloses a protected hypodermic needle comprising a receiver 25 for holding a needle 28, a protective cap 33 completely enclosing the needle, the cap movable from a first position to a second position. The device includes a clip ring 23. The receiver has a tab 40 that slides within a track 36. The cap has a tip formed with an opening and a membrane 33 formed of a material that closes the opening after the needle is pulled back from a functional position to a closed position.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4, 5-11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox in view of Asbaghi (US 2001/0031949) in view of Wilmot (US 5391151).

5. Claims 1, 5, 11, 13 differ from Fox in calling for the cap to be locked in a first functional position and movable to a second functional position. Asbaghi teaches a protective device for a

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needle comprising a cap that is locked in a first functional position (see Fig. 5B) and movable to a second functional position (see Fig. 5C) and then movable to the protected position (see Fig. 5D) allowing the needle to be inserted the desired depth into the patient without have the entire needle disposed outside of the protected cover (page 3, paragraph 0033). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Fox to include the cap positions as taught by Asbaghi to allow the needle to be inserted the desired depth into the patient without have the entire needle disposed outside of the protected cover.

6. Claims 1, 5 further differ from Fox in calling for the forward end to be formed with a guide. Wilmot teaches a sharps device encased in a cap, the cap having a conical portion 19 and a cylindrical stabilization portion 18 to lead the needle out of the cap and stabilize the needle during injection to ensure that the needle exits the device properly to maintain the integrity of the needle (Col. 3, lines 43-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gregorio to include a guide as taught by Wilmot to ensure that the needle exits the cap properly to maintain the proper functioning of the device.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims, 1, 4, 5, 12 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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